PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is to be supplied upon doctor's prescription only

OCSAAR® 50 mg
Tablets

Each tablet contains:
Losartan Potassium 50 mg

For a list of inactive ingredients refer to section 6.

Read all of this leaflet carefully before you start using this medicine.
- This leaflet contains concise information about **OCSAAR**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

1. WHAT OCSAAR IS AND WHAT IT IS USED FOR?
OCSAAR is indicated for the treatment of heart failure.
OCSAAR is also indicated for the treatment of hypertension (high blood pressure) and to help lower the risk of cardiovascular events, such as stroke, in patients with high blood pressure and a thickening of the left ventricle (the heart's main pumping chamber).
OCSAAR also provides kidney protection by delaying the worsening of kidney disease in Type-2 diabetic patients with protein in their urine (proteinuria).

THERAPEUTIC GROUP: OCSAAR is an angiotensin II receptor antagonist.

2. BEFORE YOU TAKE OCSAAR
2.1 Do not take OCSAAR if:
- you are allergic (hypersensitive) to losartan or to any of the other ingredients of this medicine (listed in section 6)
- you are more than 3 months pregnant (It is also better to avoid **OCSAAR** in early pregnancy - see section 2.5 "Pregnancy and breast-feeding")
- your liver function is severely impaired
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

2.2 Special warnings concerning use of OCSAAR
Talk to your doctor or pharmacist before taking the medicine.
You must tell your doctor if you think you are (or might become) pregnant. **OCSAAR** is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section 2.5 "Pregnancy and breast-feeding").
Before treatment with **OCSAAR**, it is important to tell your doctor if:
- you have had a history of angiooedema (swelling of the face, lips, throat, and/or tongue) (see also section 4, "Side effects"),
- you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 "How do you use **OCSAAR**?"),
- you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently,
- your liver function is impaired (see sections 2.1 "Do not take **OCSAAR** if" and 3 "How do you use **OCSAAR**?"),
- you suffer from heart failure, with or without renal impairment, or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a ß-blocker concomitantly,

- you have problems with your heart valves or heart muscle,
- you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland),
- you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
  - aliskiren

  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
  See also information in section 2.1 "Do not take **OCSAAR** if".
- you are taking other medications that may increase serum potassium (see also information in section 2.3 "Drug interaction").

2.3 Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.
Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamterene, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with **OCSAAR** is not advisable.

Take particular care if you are taking the following medicines while under treatment with **OCSAAR**:
- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofene, amifostine
- non-steroidal anti-inflammatory drugs such as indomethacin, including Cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan

Your doctor may need to change your dose and/or to take other precautions:
If you are taking an ACE-inhibitor or aliskiren (see also information in section 2.1 "Do not take **OCSAAR** if" and in section 2.2 "Special warnings concerning use of **OCSAAR**").

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

2.4 Taking OCSAAR with food and drink
OCSAAR may be taken with or without food.
Grapefruit juice should be avoided while taking **OCSAAR**.

2.5 Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking **OCSAAR** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **OCSAAR**. **OCSAAR** is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. **OCSAAR** is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is a new-born, or born prematurely.

Ask your doctor or pharmacist for advice before taking this medicine.

2.6 Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
OCSAAR is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

2.7 Important information about some of the ingredients of OCSAAR
OCSAAR tablets contain lactose (for lactose content, please refer to section 6). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
OCSAAR tablets contain potassium (for potassium content, please refer to section 6).

3. HOW DO YOU USE OCSAAR?
Always take **OCSAAR** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Your doctor will determine the dosage and duration of the treatment.
Your doctor will decide on the appropriate dose of **OCSAAR**, depending on your condition and whether you are taking other medicines. It is important to continue taking **OCSAAR** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Adult patients with High Blood Pressure
Treatment usually starts with 50 mg losartan (one tablet of **OCSAAR**) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. Sometimes, in certain patients, it might be necessary to later increase the dosage of the medicine to 100 mg losartan (two tablets of **OCSAAR**), once daily.
If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Adult patients with high blood pressure, Type 2 diabetes and protein in the urine
Treatment usually starts with 50 mg losartan (one tablet of **OCSAAR**) once a day. Sometimes, in certain patients, it will be necessary to increase the dosage of the medicine to 100 mg losartan (two tablets of **OCSAAR**), once daily, depending on the effect of the medicine on blood pressure.

Losartan may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Adult patients with Heart Failure
Treatment usually starts with 12.5 mg losartan once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. The maximal dose is 150 mg (three tablets of **OCSAAR**), once daily.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

Dosage in special patient groups
The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. Patients with severe hepatic impairment should not use losartan (see section 2.1 "Do not take **OCSAAR** if").

Do not exceed the recommended dose.

Administration

The tablets should be swallowed whole with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take **OCSAAR** until your doctor tells you otherwise.

The score line is not intended for breaking the tablet.
No information is available regarding crushing/splitting/chewing of the tablets.

If you take more OCSAAR than you should
Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take OCSAAR
If you miss a daily dose, do not take a double dose. Take the next dose as normal and ask your doctor.
Complete the full course of treatment as instructed by the doctor.

It is important to continue taking **OCSAAR** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, using **OCSAAR** can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.
Stop taking the medicine and proceed immediately to the doctor or to the nearest emergency room if the following appears:
A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing). This is a serious but rare side effect, which appears in a frequency of 1-10 patients out of 10,000. You may need urgent medical attention or hospitalisation.

The following side effects have been reported with **OCSAAR**:
Common (may affect up to 1 in 10 people):

- dizziness,
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- debility,
- fatigue,
- too little sugar in the blood (hypoglycaemia),
- too much potassium in the blood (hyperkalaemia),
- changes in kidney function including kidney failure,
- reduced number of red blood cells (anaemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon (may affect up to 1 in 100 people):

- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),

- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

Rare (may affect up to 1 in 1,000 people):
- hypersensitivity,
- angiooedema,
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation),
- brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Not known (frequency cannot be estimated from the available data):
- reduced number of thrombocytes,
- migraine,
- liver function abnormalities,
- muscle and joint pain,
- flu-like symptoms,
- back pain and urinary tract infection,
- increased sensitivity to the sun (photosensitivity),
- unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),
- impotence,
- inflammation of the pancreas (pancreatitis),
- low levels of sodium in the blood (hyponatraemia),
- depression,
- generally feeling unwell (malaise),
- ringing, buzzing, roaring, or clicking in the ears (tinnitus),
- disturbed taste (dysgeusia).

If side effect appeared, if one of the side effects gets serious or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by using the link " Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE OCSAAR?
Avoid Poisoning! This medicine, as all other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicity instructed to do so by a doctor.
Do not use **OCSAAR** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
Store below 30ºC. Protect from light.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
6.1 What OCSAAR contains
In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, lactose anhydrous, pregelatinized starch, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, titanium dioxide, carnauba wax.

OCSAAR contains 4.24 mg (0.108 mEq) potassium and 25.5 mg lactose anhydrous.

6.2 What OCSAAR looks like and contents of the pack
OCSAAR tablet is white, oval shaped, film-coated tablet, with “952” on one side and scored on the other side.
Pack sizes: 30 tablets per pack.

Manufacturer: Organon LLC, NJ USA.

License holder and address: Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba.

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Drug registration no. listed in the official registry of the Ministry of Health: 122.79.28344